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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 25436/2233 6761 10/23/2003 Larry Richard Brown 10/691,874 **EXAMINER** 27495 12/01/2004 7590 JEFFERY, JOHN A PALMER & DODGE, LLP KATHLEEN M. WILLIAMS / STR PAPER NUMBER ART UNIT 111 HUNTINGTON AVENUE BOSTON, MA 02199 3742

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

,		Applicati	on No.	Applicant(s)	
Office Action Summary		10/691,8	74	BROWN, LARRY	RICHARD
		Examine	r	Art Unit	
		John A. J		3742	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is tess than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)	Responsive to communication(s) filed on	·			×
′=	This action is <b>FINAL</b> . 2b) This action is non-final.				
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims					
4)  Claim(s) 1-47 is/are pending in the application.  4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.  5)  Claim(s) is/are allowed.  6)  Claim(s) 6-47 is/are rejected.  7)  Claim(s) is/are objected to.  8)  Claim(s) are subject to restriction and/or election requirement.					
Applicati	on Papers				
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on 23 October 2003 is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>					
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachmen	t(s)				
2) Notice 3) Information	te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-9 mation Disclosure Statement(s) (PTO-1449 or PTO or No(s)/Mail Date 20031023.		4) Interview Summary Paper No(s)/Mail D  5) Notice of Informal F  6) Other:	ate	O-152)

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#### **DETAILED ACTION**

## Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-5, drawn to a method for thermally cycling samples of biological material, classified in class 435, subclass 288.4.
- II. Claims 6-47<sup>1</sup>, drawn to an apparatus for thermally cycling biological material samples with multiple heat sources, classified in class 219, subclass 476.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as a variety of temperature control methods, not necessarily cooling the block via a convection current, and repetitively measuring, calculating, and comparing the temperature thermal block temperature as claimed in the broadest method claim.

<sup>&</sup>lt;sup>1</sup> Although claims 7-21 and 24-27 depend from claim 1, the preamble of claims 7-21 and 24-27 reciting "[t]he apparatus of claim 1" is inconsistent with the method recited in claim 1. Accordingly, the examiner presumes applicant intended claims 7-21 and 24-27 to each depend from apparatus claim 7. This presumption was confirmed in a telephone conversation with David Dykeman on Nov. 4, 2004 in conjunction with the examiner's restriction requirement. In that conversation, Mr. Dykeman elected Group II, claims 6-47 without traverse for examination.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with David Dykeman on Nov. 4, 2004, a provisional election was made without traverse to prosecute the invention of Group II, claims 6-47. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-5 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### Claim Objections

Claims 7-27 are objected to because of the following informalities:

The dependency of claims 7-21 and 24-27 must be changed to claim 6 respectively for the reasons set forth in Footnote 1 of this office action. As noted previously, claims 7-21 and 24-27 are presumed to depend from claim 6 for examination purposes. Appropriate correction is required.

# Claim Rejections - 35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 6-10, 12, 14-32, 34, and 36-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO98/43740 in view of JP3-295185. WO98/43740 discloses a polymerase chain reaction (PCR) thermal cycler with heat sink 34, sample block 36 made of silver with sample wells 20, and Peltier devices 39 clamped therebetween. See Figs. 3 and 10. The Peltier devices heat and cool the block under computer control. See abstract and P. 8-11. A layer of thermal grease is disposed on each side of the Peltier devices. See P. 12, 2nd paragraph. Note also perimeter electric heater 74 in Figs. 10 and 11. See P. 14. Moreover, a heated cover 57 applies pressure to the assembly. See P. 14-15.

The claims differ from WO98/43740 in calling for the second heat source to be below the first heat source. But locating a second electric heater below a first electric heater such that one electric heater extends beyond another to uniformly heat a block is well known in the art. JP3-295185, for example, discloses a first electric heater 10 and second electric heater in a vertical stack, each heater insulated from the other. See Fig. 1-3 and the abstract. As best seen in Fig. 2 and 4, the pattern of electric heater 10 does not overlap the pattern of electric heater 11. As a result, areas that are not directly adjacent one electric heater are directly adjacent the other heater. By filling the gaps formed by one electric heater's profile with a second, vertically-spaced electric heater,

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the block is more uniformly heated as compared to a single heater. In view of JP3-295185, it would have been obvious to one of ordinary skill in the art to provide a second heater disposed below and extend beyond the first heater in the previously described apparatus to fill the gaps formed by one electric heater's profile with a second, vertically-spaced electric heater, the block is more uniformly heated as compared to a single heater.

Regarding claims 9 and 31, although WO98/43740 teaches reducing the temperature gradient across the sample block "to an acceptable level," such an "acceptable" temperature gradient nonetheless fully meets the claimed gradient. Regarding claims 13 and 35, the perimeter heater 74 inherently heats the first heat source on its outer periphery resulting in a higher outer periphery temperature as compared to the inner periphery.

## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,657,169. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader in scope than the patented claims. *See In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). Moreover, there is no apparent reason why applicant could not have presented the instant claims during prosecution of the application that issued as '169 patent.

### Other Pertinent Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant should (1) separately consider the art, and (2) consider the art together with the previously cited prior art for potential applicability under 35 U.S.C. §§ 102 or 103 when responding to this action. US 482, US 512, US 299, US 130 US 883 disclose thermal cyclers relevant to the instant invention.

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### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John A. Jeffery whose telephone number is (703) 306-4601. The examiner can normally be reached on Monday - Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans, can be reached on (703) 305-5766. All faxes should be sent to the centralized fax number at (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)

JOHN A. JEFFERY PRIMARY EXAMINER

11/17/04